METHOD, APPARATUS AND SYSTEM FOR AUTOMATION OF BODY WEIGHT SUPPORT TRAINING (BWST) OF BIPED LOCOMOTION OVER A TREADMILL USING A PROGRAMMABLE STEPPER DEVICE (PSD) OPERATING LIKE AN EXOSKELETON DRIVE SYSTEM FROM A FIXED BASE

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application is a divisional application of Serial No. 09/643,134 filed August 21, 2000 which claims the benefit of Provisional Application Serial No.60/150,085, filed 20 August 1999.

STATEMENT REGARDING FEDERALLY SPONSORED R&D

[0002] The invention described herein was made in the performance of work under a NASA contract, and is subject to the provisions of Public Law 96-517 (35 U.S.C. §202) in which the contractor has elected to retain title.

FIELD OF INVENTION

[0003] The field of the invention is robotic devices to improve ambulation.

BACKGROUND OF THE INVENTION

[0004] There is a need to train patients who have had spinal cord injuries or strokes to walk again. The underlying scientific basis for this approach is the observation that after a complete thoracic spinal cord transection, the hindlimbs of cats can be trained to fully support their weight, rhythmically step in response to a moving treadmill, and adjust their walking speed to that of a treadmill. See, for example, Edgerton et al., Recovery of full weight-supporting locomotion of the hindlimbs after complete thoracic spinalization of adult and neonatal cats. In: *Restorative Neurology, Plasticity of Motoneuronal Connections*. New York, Elsevier Publishers, 1991, pp. 405-418; Edgerton, et al., Does motor learning occur in the spinal cord? *Neuroscientist* 3:287-294, 1997b; Hodgson, et al., Can the mammalian lumbar spinal cord learn a motor task? *Med. Sci. Sports Exerc.* 26:1491-1497, 1994.

[0005] Relatively recently, a new rehabilitative strategy, locomotor training of locomotion impaired subjects using Body Weight Support Training (BWST) technique over a treadmill has been introduced and investigated as a novel intervention to improve ambulation following neurologic injuries. Results from several laboratories throughout the world suggest that locomotor training with a BWST technique over a treadmill significantly can improve locomotor capabilities of both acute and chronic incomplete spinal cord injured (SCI) patients.

[0006] Current BWST techniques rely on manual assistance of several therapists during therapy sessions. Therapists provide manual assistance to the legs to generate the swing phase of stepping and to stabilize the knee during stance. This manual assistance has several important scientific and functional limitations. *First,* the manual assistance provided can vary greatly between therapists and sessions. The patients' ability to step on a treadmill is highly dependent upon the skill level of the persons conducting the training. *Second,* the therapists can only provide a crude estimate of the required force, torque and acceleration necessary for a prescribed and desired stepping performance. To date all studies and evaluations of step training using BWST technique over a treadmill have been limited by the inability to quantify the joint torques and kinematics of the lower limbs during training. This information is critical to fully assess the changes and progress attributable to step training with BWST technique over a treadmill. *Third,* the manual method can require up to three or four physical therapists to assist the patient during each training session. This labor-intensive protocol is too costly and impractical for widespread clinical applications.

[0007] There is a need for a mechanized system with sensor-based automatic feedback control exists to assist the rehabilitation of neurally damaged people to relearn the walking capability using the BWST technique over a treadmill. Such a system could alleviate the deficiencies implied in the currently employed manual assistance of therapists. A programmable stepper device would utilize robotic arms instead of three physical therapists. It would provide rapid quantitative measurements of the dynamics and kinematics of stepping. It would also better replicate the normal motion of walking for the patients, with consistency.

SUMMARY OF THE INVENTION

[0008] The invention is a robotic exoskeleton and a control system for driving the robotic exoskeleton. It includes the method for making and using the robotic exoskeleton and its control system. The robotic exoskeleton has sensors embedded in it which provide feedback to the control system.

[0009] The invention utilizes feedback from the motion of the legs themselves, as they deviate from a normal gait, to provide corrective pressure and guidance. The position versus time is sensed and compared to a normal gait profile. There are various normal profiles based on studies of the population for age, weight, height and other variables. While the motion of the legs is driven according to a realistic model human gait, additional mechanical assistance is applied to flexor and extensor muscles and tendons at an appropriate time in the gait motion of the legs in order to stimulate the recovery of afferent-efferent nerve pathways located in the lower limbs and in the spinal cord. The driving forces applied to move the legs are positioned to induce activations of these nerve pathways in the lower limbs that activate the major flexor and extensor muscle groups and tendons, rather than lifting from the bottom of the feet.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The above and other features and advantages of the invention will be more apparent from the following detailed description wherein:

[0011] Figure 1 shows the patient in a body weight suspension training (BWST) modality over a treadmill attached to two pairs of robotic arms, with sensors, which are computer controlled and are directed to train the patient to walk again;

[0012] Figure 2 shows another view of the legs of the patient attached to the robotic arms which have the acceleration and force/torque sensors in them;

[0013] Figure 3 shows a detail of one of the robotic arms with its rotary and telescopic motions;

[0014] Figure 4A shows the detail of the ankle and upper leg attachments, as well as a special shoe with pressure sensors in it, and also shown are stimulation means for flexor and extensor muscle groups and tendons;

[0015] Figure 4B shows a detail of corresponding to Figure 4A, except that the robotic arms and the position of the sensor units are shown, attached between the arms and the ankle and knee attachments to the leg;

[0016] Figure 5 shows a diagrammatic representation of the interactions of the sensors, treadmill speed, individual stepping models, and the computational and other algorithms which form the operating control with feedback part of the system;

[0017] Figure 6 shows the system of Figure 1 from a rear three-quarter view showing details of the keyboard, display, and hip harness system, both passive and active;

[0018] Figure 7 shows the front three-quarter view corresponding to Figures 1 and 6, showing other detail of the hip control system and the off-treadmill recording, display, and off-treadmill control part of the system;

[0019] Figure 8 shows a dual t-bar method for on-treadmill control of hip and body position.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

[0020] The following description is of the best mode presently contemplated for carrying out the invention. This description is not to be taken in a limiting sense, but is merely made for the purpose of describing the general principles of the invention. The scope of the invention should be determined with reference to the claims.

[0021] The solution to the above problem is an individually adjustable and automated BWST

[0022] technique using a Programmable Stepping Device (PSD) with model and sensing based control operating like an exoskeleton on the patients' legs from a fixed base on the treadmill (i) to replace the active and continuous participation of currently needing several highly and specifically trained therapists to conduct the retraining sessions, (ii) to provide a consistent training performance, and (iii) to establish a quantified data base for evaluating patient's progress during locomotor training.

[0023] The system serves the purpose of assisting and easing the rehabilitation of spinal cord, stroke and traumatic brain injured people (as well as

others with injury affecting locomotion) to regain , walking capabilities. The overall system uses an individually adjustable and sensing based automation of body weight support training (BWST) to train standing and locomotion of impaired patients. The system helps them to relearn how to walk on a treadmill which then facilitates relearning to walk overground. It uses an individually adjustable and sensing based automation of body weight support training (BWST) approach to train standing and locomotion of impaired patients by helping them to relearn how to walk on a treadmill which then facilitates relearning to walk overground.

[0024] Figure 1 and Figure 2 show two pairs of motor-driven mechanical linkage units, each unit with two mechanical degrees-of-freedom, are connected with their drive elements to the fixed base of the treadmill while the linkages' free ends are attached to the patient's lower extremities. Two pairs of motor-driven mechanical linkage units **101, 102, 103, 104** each unit with two mechanical degrees-of-freedom, are connected with their drive elements **105, 106, 107, 108** to the fixed base **109** of the treadmill **110** while the linkages' free ends **111, 112, 113, 114** are attached to the patient's lower extremities (legs) **A1, A2** at two locations at each leg so that one linkage pair **101, 102** serves one leg **A1** and the other linkage pair **103,104** serves the other leg **A2** in the sagittal plane of bipedal locomotion.

[0025] Thus, this linkage system arrangement **101, 102, 103, 104** is capable of reproducing the profile of bipedal locomotion and standing in the sagittal plane from a fixed base **109** which is external to the act of bipedal locomotion and standing on a treadmill **110**.

[0026] The exoskeleton linkage system together with its passive compliant elements are adjustable to the geometry and dynamic needs of individual patients.

[0027] This individual adjustment is implemented in this embodiment with the control of the linkage system of the programmable stepper device (PSD) computer **115** based, referenced to individual stepping models, treadmill **110** speed, and force/torque and acceleration data (sensors located at **111, 112, 113, 114)** sensed at the linkages' exoskeleton contact area with each of the patient's legs **111, 112, 113, 114**.

[0028] As seen in Figure 2 the system concept is built on the use of special two degree-of-freedom (d.o.f) robot arms **101, 103, 102, 104** connected to the fixed

base of the treadmill where their drive system is located, while the free end of the robot arms **111, 112, 113, 114** is connected to the patient's legs like an exoskeleton attachment.

[0029] As shown in Figure 3, the first (or base) d.o.f (degree of freedom, or, joint) of the robot arms is rotational **301, 302**, and the second (or subsequent) d.o.f , or, joint is linear of telescoping nature **303, 304**. The rotational drive elements **105, 106, 107, 108** are represented by **305** in Figure 3. The angular rotational motion indicated by the arrows **301** and **302** take place around a pivot point **306**. This motion is driven by a motor **307** which is located perpendicular to the plane of rotation **301, 302** of the telescoping arm **307,** in this aspect of this embodiment. The telescoping arm comprises an outer sleeve part **308** and an inner sleeve part **309**. In addition a motor **310** for moving the inner sleeve relative **309** to the outer sleeve **308**, which in this aspect of this embodiment is fixed to the rotating element **305**. It should be noted that there are other ways, old in the art, of achieving the two dimensional motion in a plane which the rotating **301, 302**, telescoping **303, 304** arm, as just described, which may form a different embodiment as herein presented, but which is equally good at providing the required (motor driven) degrees of freedom.

[0030] The mechanical part of the system uses four such robot arms (**101, 102**), (**103, 104**), two for assisting each leg of a patient in bipedal locomotion. The two arms are located above each other in a vertical plane coinciding with the sagittal plane of bipedal locomotion.

[0031] The rotational axis of the first joint **305** is perpendicular to the vertical (sagittal) plane while the linear (telescoping) axis **307** of the second joint is parallel to the vertical (sagittal) plane. Thus, the free end of each arm **111, 112, 113, 114** can move up-down and in-out. These motion capabilities are needed for each arm to jointly reproduce the profile of bipedal locomotion in the sagittal plane from a fixed treadmill **110** base **109** which is external to the act of bipedal locomotion on a treadmill **110**.

[0032] Figure 4 shows the patients leg **A1**. A leg support brace **400** is attached to the part of the leg **A1** which is above **403** the knee and to the part of the leg below **404** the knee. As shown there is a freely pivoting pivot joint **401** corresponding the motion of the knee. The leg brace may correspond to a modified

commercially available brace such as the C180 PCL (posterior tibial translation) support offered by Innovation Sports, with a modification. The modification to the leg support brace is shown as **407**. The ankle has a padded custom-made attachment. In addition, a special shoe **405** containing pressure sensors **406** is used on the foot to provide feedback information to the main computer **115**.

[0033] The arms **101** and **102** attach respectively for patient's leg **A1** at the sensor **451** at the knee via the modification **407** and to the ankle area sensor **452**. The exoskeleton supports and moves each leg so as to provide pressure on extensor surface during stance and flexor surface during swing. The extensor pressure is applied inferior to the patella in the vicinity of the patella tendon which helps locks the knee so as to aid "stance"position of the leg. The flexor pressure is applied in the vicinity of the hamstring muscles and associated tendons, on the back of the upper leg just above the rear crease of the knee, aiding in the "swing" part of the step motion.

[0034] An important additional feature is the continuous recording of the electrical activity of the muscles in the form of electromyograms (EMGs). These are real-time recordings of the electrical activity of the muscles measured with surface electrodes, or, optionally, with fine wire electrodes, or with a mix of electrode types.

[0035] The two arms **101, 102** assisting one leg are connected to the leg so that the lower arm is attached to the lower limb slightly above the ankle while the upper

[0036] arm is attached to the leg near and slightly below the knee. This robot arm arrangement closely imitates a therapist's two-handed interaction with a patient's one leg **A1** during locomotor training on a treadmill. Implied in this robot arm arrangement is the fact that the lower arm **102** is mostly responsible for the control of the lower limb while the upper arm **101** is mostly responsible for the upper limb control, though in a coordinated manner, complying with the profile of bipedal locomotion in the sagittal plane as seen from the front.

[0037] At the front end of each robot arm **101, 102, 103, 104** near the exoskeleton connection to the leg a combined force/torque and acceleration sensor **451, 452** (other two sensors of this type not shown) is mounted which measures the robot arm's interaction with the leg. Potentiometers **350** measuring the arm's position are installed at the drive motors at the base of the robot arms. Alternative methods,

old in the art, also may be used, including but not limited to, a digitally-read rotating optical disk **351**.

[0038] The mechanical elements necessary to properly connect to a variety of legs are adjustable to the geometry of individual patients, including the compliant elements of the system. The described four-arm architecture permits all active drive elements of each arm (motors, electronics, computer) to be housed on the front end of the treadmill **110** in a safe arrangement and safe operation modality. Aspects of the safe operation modality include limiting switches on the range of motion of the telescoping movements and in the rotating movements of the arms, emergency cut-off switches for both a monitoring therapist and for the patient. In addition, the leg brace **400** is constructed so that the pivoting joint **401** cannot be bent back so as to hyperextend the knee and destroy it. The overall construction of the leg brace **400** is such that it can resist a chosen safety factor, such as four times (4X), the maximum amount of force which the robotic arms with all their motors, can exert to buckle the knee, i.e., the constructed knee joint (for the C180, it is a four bar linkage), which protects the knee from hyperextension.

[0039] The range of kinematic and dynamic parameters associated with the programmable stepping device (PSD) operation are determined from actual measurements of the therapists' interaction with the legs of various patients during training and from the ideal models, Figure 5, **551**, **552** of corresponding healthy persons' bipedal locomotion. The system can monitor and control each leg independently.

[0040] The control system (Figure 5, **500**) of the PSD is not wired to patients body but rather gets feedback from sensors in the vicinity of the ankles (Figure 4B) **452**, the knees **451** and from the (dynamic) pressure sensors **406** in the"shoes" of the apparatus.

[0041] The control system (Figure 5, **500**) is computer based and referenced to (i) individual stepping models **551**, **552**, (ii) treadmill speed **561**, and (iii) force/torque/accelerometer sensor data **541**, **542** measured at the output end of each robot arm. The control software architecture **571**, **572** is "intelligent" in the sense that it can distinguish between the force/torque generated by the patient's muscles, by

the treadmill **110**, and by the robot arms' drive motors **310** (others not shown) in order to maintain programed normal stepping on the treadmill.

[0042] The patient's contact force with the revolving treadmill belt is pre-adjustable through the BEST harness (Figure 6, Figure 7, **600)** dependent upon body weight and size. The proper adjustment can be automatically maintained during motion by utilizing a proper force/pressure system on the harness **600**. The harness system may be passive with respect to the hip placement of the patient, in so far as it provides for constraint via somewhat elastic belts, or cords, (Figure 6) **621**, **622**, **623**; (Figure 7) **624**. A more active adjustment system is also used , in a different aspect of an embodiment of this invention. Figure 8 shows the use of dual T-bars **801** and **802** where the T-bars are adjustable, as shown by the curved and straight arrows, by controlled motors **821**, **822**, **823**, **824.** Other active methods of control of the hips, utilize stepping, or other, motors on the belts (Figure 6) **621**, **622**, **623**, as **6211**, **6221**, **6231**) and (Figure 7) **624** as **6241**. The use of special sensor **406** shoes **405** also provides feedback for the adjustment of body weight in contact with the treadmill **110**. The overall control system operates in a wireless configuration relative to the patient's body. The algorithms for the system include, in some aspects of an embodiment of the invention, neural network algorithms, in software and/or in hardware implementation, to "learn" aspects of the patient's gait, either when strictly mediated by the robotic system, or, when therapists move the patient through the "proper motions" while the robotic system is acting passively, except for measurements being made by sensors **406** and **451** and **452** and the electromyogram (EMG)s and the corresponding sensors on the other leg (not shown).

[0043] A keyboard (Figure 6, **701**) and monitor (Figures 6, 7) **702** attached to the treadmill **110** enables the user to input selected kinematic and dynamic stepping parameters to the computer-based control and performance monitor system. The term user, here, covers the patient and /or a therapist and/or a physician and/or an assistant. The user interface to the system is implemented by a keybord/monitor setup **701**, **702** attached to the front of the treadmill **110**, easily reachable by the patient, as long as the patient has enough use of upper limbs. It enables the user (therapist or patient) to input selected kinematic and dynamic stepping parameters and treadmill speed to the control and monitor system. A condensed stepping performance can also

be viewed on this monitor interface in real time, based on preselected performance parameters.

[0044] An externally located digital monitor system **731** displays the patient's stepping performance in selected details in real time.

[0045] A data recording system **741** enables the storage of all training related and time based and time coordinated data, includingelectromylogram (EMG) signals, for off-line diagnostic analysis. The architecture of the data recording part of the system enables the storage of all training related and time based and time coordinated data, including electromyogram (EMG), torque and position signals, for off-line diagnostic analysis of patient motion, dependencies and strengths, in order to provide a comparison to expected patterns of nondisabled subjects. The system will be capable of adjusting or correcting for measured abnormalities in the patient's motion.

[0046] An important part of this embodiment of the invention is the provision for the extra-stimulation of designated and associated tendon group areas. For example, when the leg is being raised, flexor and associated tendons in the lower hamstring area on the back of the leg are optionally subject to vibration or another type of extra-stimulation.(See Figure 4A, **471**, **472**) This is thought to strengthen the desired nerve pathways to allow the patient to develop toward overground locomotion. Therapeutic stimulators **471**, **472**, which may be vibrators, is shown in Figure 4A.

[0047] The overall system is designed to minimize the external mechanical load acting on the patient while maximizing the work performed by the patient to generate effective stepping and standing during treadmill training.

[0048] Operation safety is assured by proper stop conditions implemented in the control software and in the electrical and mechanical control hardware. The patient's embarkment to and disembarkment from the Programmable Stepping Device (PSD) is a manual operation in all cases.

[0049] While the invention herein disclosed has been described by means of specific embodiments and applications thereof, numerous modifications and variations could be made thereto by those skilled in the art without departing from the scope of the invention set forth in the claims.